

2. Throughout the relevant time period, Defendants have uniformly represented that the Product is “clinically tested” to “improve[] memory” and “support[]: healthy brain function, sharper mind, and clearer thinking”; and that Prevagen is “clinically tested” to “improve memory within 90 days”.

3. These representations are false and materially misleading. The Product has not been clinically tested, nor does it provide the stated brain and memory support. As described herein, the Products have not been subject to the required randomized, clinical trials. In addition, the testing that has been undertaken does not support Defendants’ representations.

4. Plaintiff brings this case on behalf of herself, a National Class, and a New Jersey Subclass (defined *infra.*) to recover damages for Defendants’ violation of the New Jersey Consumer Fraud Act, § 56:8-1 *et seq*; for Defendants’ violation of the New Jersey Truth-In-Consumer Contract, Warranty and Notice Act, N.J. Stat. Ann. § 56:12-15; and for disgorgement of Defendants’ unjust enrichment.

PARTIES

5. Plaintiff Elaine Spath is a resident of Morris County, New Jersey. On at least one occasion during the Class Period (as defined below), Plaintiff purchased Prevagen, including in approximately June 2015 at a CVS store located in Ledgewood, New Jersey for personal, family, or household purposes. The label of the Product represented that it was, among other things, “clinically tested” as described herein, and “support[ed]: healthy brain function, sharper mind, clearer thinking.” Plaintiff’s claim is typical of all class members in this regard.

6. Defendant Quincy Bioscience Holding Company, Inc., is a Wisconsin corporation with its principal place of business located at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience Holding Company, Inc. transacts or has transacted business in

this District and throughout the United States. At all times relevant to this Complaint, acting alone or in concert with others, Quincy Bioscience Holding Company, Inc., through its wholly-owned subsidiaries, has advertised, marketed, promoted, distributed, and sold Prevagen to consumers throughout the United States, including New Jersey.

7. Defendant Quincy Bioscience, LLC is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin limited liability company, with its principal place of business located at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience Holding Company, LLC transacts or has transacted business in this District and throughout the United States. At all times relevant to this Complaint, acting alone or in concert with others, Quincy Bioscience, LLC has advertised, marketed, promoted, distributed, and sold Prevagen to consumers throughout the United States, including New Jersey.

8. Defendant Prevagen, Inc., also doing business as Sugar River Supplements, is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin corporation, with its principal place of business located at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Prevagen, Inc. transacts or has transacted business in this District and throughout the United States. At all times relevant to this Complaint, acting alone or in concert with others, Prevagen, Inc. has advertised, marketed, promoted, distributed, and sold Prevagen to consumers throughout the United States, including New Jersey.

9. Defendant Quincy Bioscience Manufacturing, LLC, is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin corporation with its principal place of business located at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience Manufacturing, LLC transacts or has transacted business in this District and throughout the United States. At all times relevant to this Complaint, acting alone or in concert

with others, Quincy Bioscience Manufacturing, LLC has advertised, marketed, promoted, distributed, and sold Prevagen to consumers throughout the United States, including New Jersey.

10. Defendants and their agents promoted, marketed and sold the Products at issue in this jurisdiction and in this judicial district. The unfair, unlawful, deceptive, and misleading marketing, advertising and labeling of the Products was prepared and/or approved by Defendants and their agents, and was disseminated by Defendants and their agents through labeling, marketing and advertising containing the misrepresentations alleged herein. On information and belief, Defendants acted in concert to commit the acts and violations alleged herein.

JURISDICTION AND VENUE

11. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed class; (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims of the proposed class members exceed \$5,000,000 in the aggregate.

12. This Court has personal jurisdiction over Defendants, as Defendants have had more than minimum contacts with the State of New Jersey, and have availed themselves of the privilege of conducting business in this state and through sales of the Products to New Jersey consumers. In addition, as explained herein, Defendants have committed affirmative tortious acts within the State of New Jersey that give rise to civil liability, including distributing the Products for sale throughout the State of New Jersey.

13. Venue is proper in this forum pursuant to 28 U.S.C. § 1391(b) and 18 U.S.C. § 1965 because a substantial part of the events giving rise to Plaintiff's injuries occurred in this District and because Defendants are not residents of this State.

ALLEGATIONS OF FACT

Defendants' Marketing and Sale of Prevagen

14. Defendants manufacture, sell, distribute, advertise and market Prevagen.
15. The Products are marketed and labeled as a supplement that provides key brain health benefits, including improving age-related memory loss.
16. Prevagen is sold in virtually every major food, drug, and mass retail outlet in the country. It is also sold online on Defendants' website.
17. Prevagen is available in regular strength, extra strength, mixed berry flavor chewable, and mixed berry flavor extra strength chewable forms. The regular strength and mixed berry flavor products contain 10 mg of apoaequorin per serving, while the extra strength product contains 20 mg of apoaequorin per serving:



18. Throughout the relevant time period, Defendants have uniformly represented that the Product is “clinically tested” to “improve[] memory” and “support[]: healthy brain function, sharper mind, and clearer thinking”; and that Prevagen is “clinically tested” to “improve memory within 90 days”. This, in fact, is not true. The Product is not clinically tested, nor does it provide the stated brain and memory support.

Defendants' Representations that the Product Has Been Clinically Tested Are False

19. Prevagen is a dietary supplement.

20. Dietary supplements are governed by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). Pursuant to DSHEA, a supplement manufacturer may only make claims concerning how a product affects the structure or function of the body without obtaining prior FDA approval if certain requirements are met, including that the manufacturer is able to substantiate that the claims are truthful and not misleading. 21 U.S.C. § 343(r)(6)(B).

21. Further, the FDA has adopted the FTC's substantiation standard of "competent and reliable scientific evidence" for dietary supplements.¹

22. The universally accepted form of scientific evidence recognized by experts in the field for determining whether a substance provides any human health benefit is by demonstrating its value over placebo through high quality and well-conducted randomized controlled clinical trials ("RCTs").² Also, it is generally recognized that RCTs that are of sufficient quality to be relied upon for reaching efficacy conclusions should be subjected to a peer review process and published in a peer reviewed journal.

23. Competent and reliable scientific evidence is defined as: "tests, analysis, research, studies, or other evidence based on the expertise of professionals in the relevant area that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."³ For products such as Prevagen, adequate substantiation, as required by experts in the relevant area,

¹ See Guidance for Industry Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (Dec. 2008) (<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm>) (last visited Aug. 19, 2016) ("FDA Guidance for Industry").

² See e.g. 21 CFR 314.126.

³ See FDA Guidance for Industry.

consists of high quality RCTs—particularly when representations regarding health affects is the subject matter.⁴

24. Defendants represent and have represented to consumers through an extensive and uniform nationwide marketing campaign, including on the Product packages, that the Products are “clinically tested” to “improve[] memory” and “support[]: healthy brain function, sharper mind, and clearer thinking”; and that Prevagen is “clinically tested” to “improve memory within 90 days” (collectively “Brain and Memory Support” representations).

25. As alleged in this Complaint, these representations are false and unlawful. The Products have not actually been “clinically tested.” By claiming that the Product is clinically tested, Defendants are representing to consumers that credible scientific evidence supports Defendants’ statements that the Products provide the stated brain function and memory benefits. Specifically, Defendants are representing that they have conducted high quality, randomized clinical trials, which have been subjected to peer review. In fact, Defendants have conducted no such testing.

26. The only test sponsored by Defendants that may have been randomized, the Madison Memory Study (the “Study”), is unreliable and flawed. Based on the data presented, Defendants primarily relied on one double-blind, placebo-controlled human clinical study using objective measures of cognitive function. The study involved 218 subjects taking either 10 milligrams of Prevagen or a placebo. The subjects were assessed on nine computerized cognitive tasks, designed to assess a variety of cognitive skills, including memory and learning, at various intervals over a period of 90 days. The Study shows that Prevagen does not improve memory.

⁴ 21 CFR 314.126.

27. After failing to find a treatment effect for the sample as a whole, the researchers conducted more than 30 post hoc analyses of the results, examining data broken down by several variations of smaller subgroups for each of the nine computerized cognitive tasks. This methodology greatly increased the probability that some statistically significant differences would occur by chance alone. Even so, the vast majority of these post hoc comparisons failed to show statistical significance between the treatment and placebo groups, and the few positive findings on isolated tasks for small subgroups of the study population do not provide reliable evidence of a treatment effect. The post hoc analyses of the results show the Prevagen does not improve memory.

28. As later admitted by Defendants “no statistically significant results were observed over the entire [S]tudy population” According to Defendants’ own results, the Study demonstrates that the Products are only effective in certain subgroups of the population “with either minimal or no cognitive impairment.” However, the Study was not reported until August 1, 2016, thus, for a substantial period of the Class Period, Defendants had reported no randomized clinical testing.

29. By selling the Products without the requisite competent and reliable scientific evidence/substantiation Defendants have failed to comply with the standards set forth under DSHEA, have violated the NJCFA, N. J. Stat. Ann. § 56:8-1 *et seq.*, have violated the TCCWNA”), N.J. Stat. Ann. § 56:12-15, and have been unjustly enriched.

30. Plaintiff and Class Members have been and will continue to be deceived and/or misled by Defendants’ representations that the Products are “clinically tested” when they do not meet the basic industry standard for such testing. Plaintiff and Class members have been damaged in their purchases of the Products.

31. Had Plaintiff and Class Members known the truth about Defendants' false and misleading statements, they would not have purchased the Products or would have purchased them on different terms.

Defendants' Claims Regarding Brain and Memory Support Are False And Misleading

32. Defendants state on the Product labels and in advertising that the Products are "clinically tested" to "improve[] memory" and "support[]: healthy brain function, sharper mind, and clearer thinking" and that Prevagen is "clinically tested" to "improve memory within 90 days. These statements are false and misleading.

33. In addition to being false and misleading in general, Defendants unlawfully and falsely and misleadingly represented the results of the Study in their advertising. For example, Defendants' advertising campaign pictured a chart on the labels for the Products and in Defendants' television advertisements and Internet website, prevagen.com. Defendants falsely and misleadingly represented that a "double-blinded, placebo-controlled study" showed dramatic improvement in recall tasks when, in fact, the results for the specific task referenced in the chart showed that Prevagen does not improve memory. In addition, Defendants eliminated from the chart one of the four data points in the study. At day 60, the recall task scores of subjects taking Prevagen actually declined from day 30, and were slightly worse than the recall tasks scores of subjects in the placebo group. The advertising and labeling, however, does not account for—and falsely represent—this data.

34. In addition, Defendants' clinical studies show that the claims on the side label of the Products are false: "Prevagen (apoeaquorin) is clinically shown to help with mild memory problems associated with aging" and "In clinical studies Prevagen improved memory within 90 days."

35. Defendants' clinical studies also show that the claim on the back label is false: "In a computer assessed, double-blinded, placebo-controlled study, Prevagen improved memory."

36. Defendants' clinical studies further show that the claim in the Prevagen television advertisement "Jellyfish Protein" is false: "Prevagen supplements these proteins and has been clinically shown to improve memory."

37. Defendants' clinical studies also show the these claims in the Website capture from Prevagen.com (August 18, 2016) are false: "Prevagen is clinically shown to help with mild memory problems associated with aging" and "Prevagen has been clinically tested and shown to improve mild memory problems that occur in aging."

38. As such, Defendants have engaged in false, deceptive, and misleading marketing and advertising practices in violation of the NJCFA and the New Jersey Truth-In-Consumer Contract, Warranty and Notice Act ("TCCWNA"), N.J. Stat. Ann. § 56:12-15 and have been unjustly enriched.

39. Plaintiff and Class Members have been and will continue to be deceived or misled by Defendants' brain and memory support representations. Plaintiff and Class Members have been damaged in their purchases of the Products and have been deceived into purchasing Products that they believed, based on Defendants' uniform, material misrepresentations, provided brain and memory support, when they did not.

CLASS ALLEGATIONS

40. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of herself, on behalf of all others similarly situated, and as a member the Classes defined as follows (collectively, the "Class"):

All citizens of the United States who, within the relevant statute of limitations periods, purchased Defendants' Products ("Nationwide Class"); and

All citizens of New Jersey who, within six years prior to the filing of the initial Complaint, purchased Defendant's Products ("New Jersey Subclass").

41. Excluded from the Class are: (a) federal, state, and/or local governments, including, but not limited to, their departments, agencies, divisions, bureaus, boards, sections, groups, counsels, and/or subdivisions; (b) any entity in which Defendants have a controlling interest, to include, but not limited to, their legal representative, heirs, and successors; (c) all persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and (d) any judicial officer in the lawsuit and/or persons within the third degree of consanguinity to such judge.

42. Upon information and belief, the Class consists of at least thousands of purchasers. Accordingly, it would be impracticable to join all Class Members before the Court.

43. There are numerous and substantial questions of law or fact common to all of the members of the Class that predominate over any individual issues. Included within the common questions of law or fact, but not limited to, are:

- a. Whether the "clinically tested" claims on the Products' labels are false, misleading, and deceptive;
- b. Whether Defendants' representations that the Products "improve[] memory" and "support[]: healthy brain function, sharper mind, and clearer thinking;" are false, misleading, and deceptive;
- c. Whether Defendants violated the NJCFA;
- d. Whether Defendants violated the TCCWNA; and

e. The proper measure of damages sustained by Plaintiff and Class Members.

44. Plaintiff's claims are typical of the claims of Class Members, in that they share the above-referenced facts and legal claims or questions with Class Members, there is a sufficient relationship between the damage to Plaintiff and Defendants' conduct affecting Class Members, and Plaintiff has no interests adverse to the interests of other Class Members.

45. Plaintiff will fairly and adequately protect the interests of Class Members and has retained counsel experienced and competent in the prosecution of complex class actions, including complex questions that arise in consumer protection litigation.

46. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all Class Members is impracticable and no other group method for adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:

- a. The claims presented in this case predominate over any questions of law or fact affecting any individual member of the Class;
- b. Absent a Class, the Class Members will continue to suffer damage and Defendants' unlawful conduct will continue without remedy, while Defendants profit from and enjoys their ill-gotten gains;
- c. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Defendants committed against them, and absent Class Members have no substantial interest in individually controlling the prosecution of individual actions;

- d. When the liability of Defendants has been adjudicated, claims of all Class Members can be administered efficiently and/or determined uniformly by the Court; and
- e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiff and members of the Class can seek redress for the harm caused to them by Defendants.

47. Because Plaintiff seeks relief for the entirety of the Class, the prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendants.

48. Further, bringing individual claims would overburden the Courts and be an inefficient method for resolving the dispute that is the center of this litigation. Adjudications with respect to individual members of the Class would, as a practical matter, be dispositive of the interests of other members of the Class who are not parties to the adjudication and may impair or impede their ability to protect their interests. As a consequence, class treatment is a superior method for adjudication of the issues in this case.

CLAIMS FOR RELIEF
First Claim for Relief

Violation of New Jersey Consumer Fraud Act
(for the New Jersey Subclass)

49. Plaintiff repeats and re-alleges the allegations of the preceding paragraphs as if fully set forth herein.

50. New Jersey's Consumer Fraud Act prohibits "[A]ny unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, and/or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise ... whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice. § 56:8-2, NJCFA.

51. Defendants' conduct as described above constitutes unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, and/or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise in that Defendants materially misrepresent that: (1) the Products were "clinically tested" when, in fact, they were not sufficiently tested to contain such a statement; (2) the Products "improve[] memory" and "support[]: healthy brain function, sharper mind, and clearer thinking;" and (3) the Products are "clinically tested" to "improve memory within 90 days".

52. As described above, each of these statements is false and misleading because the Products have not been subjected to the necessary testing, and do not in fact provide the stated improvement in brain and memory function. The uniform, material statements made by Defendants were false and misleading and had and continue to have the capacity to deceive and did deceive the public and cause injury to Plaintiff and the Class.

53. Plaintiff and Class Members purchased the Products for personal, family, or household purposes.

54. The advertisement, promotion, distribution, supply and/or sale of the Products is a “sale or advertisement” of “merchandise” governed by the NJCFA.

55. Defendants’ conduct was carried out with a lack of good faith, honesty in fact and observance of fair dealing.

56. Had Plaintiff and Class Members known the truth about Defendants’ false and misleading statements about the Products, they would not have purchased the Products, or would have purchased them on different terms.

57. As a direct and proximate result of Defendants’ conduct, Plaintiff and Class Members have suffered an ascertainable loss.

Second Claim for Relief

Violations of the New Jersey Truth-In-Consumer Contract, Warranty and Notice Act (for the New Jersey Subclass)

58. Plaintiff repeats and re-alleges the allegations of the preceding paragraphs as if fully set forth herein.

59. N.J. Stat. Ann. § 56:12-15 (the “TCCWNA”) provides:

No seller, lessor, creditor, lender or bailee shall in the course of his business offer to any consumer or prospective consumer or enter into any written consumer contract or give or display any written consumer warranty, notice or sign after the effective date of this act which includes any provision that violates any clearly established legal right of a consumer or responsibility of a seller, lessor, creditor, lender or bailee as established by State or Federal law at the time the offer is made or the consumer contract is signed or the warranty, notice or sign is given or displayed.

60. The labels and marketing and advertising matters for the Products are written consumer contracts, warranties, notices, and/or signs that are offered, given, and/or displayed to consumers and prospective consumers subject to the TCCWNA.

61. Plaintiff and Class Members are “consumer[s] or prospective consumer[s]” within the meaning of N.J. Stat. Ann. § 56:12-15.

62. Defendants are “sellers” within the meaning of N.J. Stat. Ann. § 56:12-15.

63. The right of consumers to truthful and accurate statements on the labels and marketing and advertising materials for the Products, as well as the right to avoid deception caused by false and misleading statements on such labels and marketing and advertising materials, are “clearly established legal rights” under N.J. Stat. Ann. § 56:8-2.

64. The responsibility of a seller to refrain from the employment of any unconscionable commercial practice, deception, fraud, false pretense, and/or misrepresentation, and to refrain from knowing concealment, suppression, and/or omission of any material fact with intent that others rely upon such concealment, suppression, and/or omission in connection with the sale of merchandise, and to refrain from selling products with labels that make false statements about the products, is clearly established under N.J. Stat. Ann. § 56:8-2.

65. Defendants violated the TCCWNA by falsely representing, advertising, marketing, selling, and distributing the Products as described herein, including by misrepresenting that Products were “clinically tested” when, in fact, they were not sufficiently tested to contain such a statement; that the Products “improve[] memory” and “support[]: healthy brain function, sharper mind, and clearer thinking” when they do not; and that the Products are “clinically tested” to “improve memory within 90 days” when they in fact do not. The Products as sold were therefore worth less than the Products as represented.

66. These affirmations and promises were part of the basis of the bargain under which Plaintiff and Class Members purchased the Products and were material factors in inducing Plaintiff and Class Members to purchase the Products.

67. Pursuant to N.J. Stat. Ann. § 56:12-17, Defendants violated the TCCWNA by promoting, distributing, and selling Products to Plaintiff and Class Members that did not conform to the promises or affirmations of fact made on, among other things, the label of the Products as alleged herein.

68. As a proximate result of Defendants' breach, Plaintiff and members of the Class sustained actual damages, including but not limited to the purchase price of the Products, the premium paid for the Products, and/or the difference between the actual value of the Products and the value of the Products if they had been as represented.

69. Plaintiff, on behalf of herself and the Class, is entitled to damages and other legal and equitable relief including, a right of reimbursement, as well as reasonable costs, expenses and attorneys' fees.

Third Claim for Relief

Unjust Enrichment (for the Nationwide Class and New Jersey Subclass)

70. Plaintiff repeats and re-alleges the allegations of the preceding paragraphs as if fully set forth herein.

71. By purchasing the Products, Plaintiff and the Class members conferred a benefit on Defendants in the form of the purchase price of the Products.

72. Defendants had knowledge of such benefits.

73. Defendants appreciated the benefit because, were consumers not to purchase the Products, Defendants would not generate revenue from the sales of the Products.

74. Defendants' acceptance and retention of the benefit is inequitable and unjust because the benefit was obtained by Defendants' fraudulent and misleading representations about the Products.

75. Equity cannot in good conscience permit Defendants to be economically enriched for such actions at Plaintiff's and Class Members' expense, and therefore restitution and/or disgorgement of such economic enrichment is required.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all similarly situated persons, prays the Court:

- a. Grant certification of this case as a class action and certify the Nationwide Class and New Jersey Subclass;
- b. Appoint Plaintiff as Class Representative and Plaintiff's counsel as Class Counsel;
- c. Award, as appropriate, actual, compensatory and monetary damages, restitution or disgorgement to Plaintiff and the Class for all causes of action;
- d. Require Defendants to immediately cease and desist from selling their misbranded Products in violation of law; enjoin Defendants from continuing to label, market, advertise, distribute, and sell the Products in the unlawful manner described herein; and order Defendants to engage in corrective action;
- e. Award attorneys' fees and costs;
- f. Award punitive damages;
- g. Award pre-and post-judgment interest; and
- h. For any and all such other and further relief as may be just and proper.

Dated this 31st day of July 2018.

ELAINE SPATH, Individually, and on Behalf of All
Similarly Situated Individuals, Plaintiff

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